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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,352	02/23/2004	Aaron T. Timperman	22085/2102	2338
29932	7590	08/05/2004	EXAMINER	
PALMER & DODGE, LLP PAULA CAMPBELL EVANS 111 HUNTINGTON AVENUE BOSTON, MA 02199			BARTON, JEFFREY THOMAS	
			ART UNIT	PAPER NUMBER
			1753	
DATE MAILED: 08/05/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/784,352	Applicant(s) TIMPERMAN, AARON T.	
	Examiner Jeffrey T Barton	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Drawings

1. Figures 1 and 2 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: on page 9, line 15, a word, such as "flow" or "force" appears to have been omitted after "electroosmotic".

Appropriate correction is required.

3. The use of the trademark TRITON X-100 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology (i.e. 4-(1,1,3,3-Tetramethylbutyl)phenyl-polyethylene glycol).

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2, 15, 25, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are limited to a "first channel compris[ing] a slight charge", and depend from claims limited to "a first uncharged channel." It is unclear whether uncharged or slightly charged channels are intended, and to what degree channels in the claimed devices and methods can be charged.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under

the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 2, 6-9, 11, 12, 15, 19-22, 24, 25, 29, 30, 32-34, 38, 39, and 41 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Xue et al.

Addressing claims 1 and 12, Xue et al disclose a microfluidic bi-directional capillary electrophoresis device (Figure 7b), comprising: a middle column (24 and 25), the middle column intersecting a first channel and a second channel (26 and 27) at a point wherein the middle column is approximately perpendicular to the first and second channels (23), a negative electrode in communication with the first channel and a positive electrode in communication with the second channel (33), wherein a mixture of anions and cations may be separated by drawing them towards the electrodes of opposite polarity.

Addressing claims 24 and 33, Xue et al disclose a method of separating a sample of anions and cations in a microfluidic capillary system, comprising: delivering the sample to the middle column of the device described above in addressing claims 1 and 12 (Paragraph 0071 - sample in 28 and vacuum applied to 29 would lead to sample traveling through channels 24 and 25), positioning negative and positive electrodes (33) in communication with the first and second channels, thereby drawing anions and cations into the channel corresponding to the electrode of opposite polarity (Paragraph 0071, Figure 9)

Further addressing claims 1, 12, 24, and 33, and addressing claims 2, 15, 25, and 34, Xue et al do not explicitly address the amount of charge present on the walls of the first and second channels. However, their example of Paragraph 0071 and Figure 9 shows elution of anions and cations into opposite channels, indicating substantial absence of electroosmotic flow, and therefore, either uncharged or slightly-charged channel walls, as supported by the specification of the instant application (Page 8, lines 11-18). Additionally, any surface in contact with a polar solution and subjected to an electric field will carry some degree of charge, strictly speaking. (e.g. acidic silanol groups in glass, trapped polar impurities in nonpolar polymers, or induced polarization) The disclosed apparatus of Xue et al successfully performs the same function with the same structure as in the instant claims, and thus the separation channels must possess similar charge characteristics. Any further reduction of channel charge would constitute an obvious improvement, because it would provide faster anion migration, given a net negative channel charge.

Addressing claims 6, 7, 19, 20, 29, 30, 38 and 39, Xue et al disclose first and second detectors in communication with the first and second channels, for the detection of cations and anions, respectively. (Detectors 52 and 53, Figure 7B; Paragraph 0054)

Addressing claims 8, 21, 32, and 41, Xue et al disclose hydrodynamic flow resistance through variation of cross-sectional area in any or all channels. (Paragraph 0038)

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Addressing claims 9 and 22, Xue et al disclose devices comprising a pressure outlet. (Paragraphs 0034 and 0040; Line 47, Figure 2)

Addressing claim 11, Xue et al disclose the first channel being a capillary. (Paragraphs 0038 and 0039; dimensions are such that the channels can be termed capillaries)

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 3-5, 16-18, 26-28, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xue et al in view of Karger et al.

Xue et al disclose devices and methods as disclosed above in addressing claims 1, 12, 24, and 33.

Xue et al do not explicitly disclose coated first channel (Claims 3, 16, 26, and 35) or coated second channel (Claims 4, 17, 27, and 36), or a first channel coated with Triton X-100. (Claims 5, 18, 28, and 37)

Karger et al disclose capillary channels that have been coated with Triton X-100 in order to reduce electroosmosis in electrophoretic separations. (Column 5, lines 3-39)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the devices and methods of Xue et al by coating the first and second channels (26 and 27) with Triton X-100, as taught by Karger et al, because it would reduce electroosmosis.

10. Claims 10, 23, 31, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xue et al in view of Kopf-Sill et al.

Xue et al disclose devices and methods as disclosed above in addressing claims 1, 12, 24, and 33.

Xue et al do not explicitly disclose the use of a dual-channel detector in communication with the first and second channels.

Kopf-Sill et al disclose the use of multichannel detectors in communication with one or more channels within their microfluidic device. (Figure 13; Paragraphs 0036 and 0088)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the devices and methods of Xue et al by adjusting the position of channels 26 and 27 such that they ran parallel and adjacent to each other and positioning a dual channel detector in communication with the channels, as taught by Kopf-Sill et al, because it would eliminate the need for multiple detectors.

11. Claims 13, 14, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xue et al in view of Lee et al.

Xue et al disclose devices and methods as disclosed above in addressing claims 12 and 33.

Xue et al do not explicitly disclose the engagement of the first and/or second channels to microfluidic systems for proteome analysis.

Lee et al disclose microfluidic systems for two-dimensional protein separations in proteome analysis (e.g. Figure 3, Paragraph 0033)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the devices and methods of Xue et al by placing the channels (26 and 27) in communication with sample inlets to proteome analysis systems, such as those taught by Lee et al, because it would provide a more powerful analytical tool with an additional dimension of separation.

Conclusion

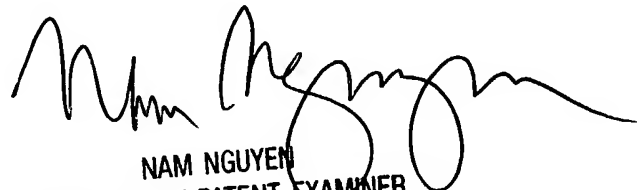
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
July 30, 2004



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